Protraction headgear compliance and orthognathic surgery in patients with cleft lip and palate

by

Cleo J. Yi

BS, University of Washington, 2013

DMD, Case Western Reserve University, 2018

Submitted to the Graduate Faculty of the

School of Dental Medicine in partial fulfillment

of the requirements for the degree of

Master of Dental Science

University of Pittsburgh

2021

UNIVERSITY OF PITTSBURGH

SCHOOL OF DENTAL MEDICINE

This thesis was presented

by

Cleo J. Yi

It was defended on

April 16, 2021

and approved by

Lindsay Schuster, DMD, MS, Clinical Assistant Professor, Department of Pediatric Plastic Surgery

John Burnheimer, DMD, MS, MPH, Assistant Professor, Department of Orthodontics and Dentofacial Orthopedics

Nilesh Shah, PhD, Assistant Professor, Department of Dental Public Health

Thesis Advisor/Dissertation Director: Lindsay Schuster, DMD, MS, Clinical Assistant Professor, Department of Pediatric Plastic Surgery

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Cleo J. Yi, BS, DMD

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Objective: The aim of this study is to assess cephalometric parameters and the need for orthognathic surgery (OS) and its relationship with protraction headgear (PHG) compliance.

Method: 23 patients with nonsyndromic cleft lip and palate and history of lip and palate repair were treated with PHG and orthodontic treatment. PHG lasted 7.4 months on average and was prescribed with 170-gram elastics worn daily for at least 12 hours. Cephalometric measurements at initial (T1), post-PHG (T2), and pre-surgical or post-orthodontic treatment (T3) of at least age 15 for females and 17 for males and the presence of OS were compared.

Results: 83% (19) of patients reported compliance with therapy. Of those compliant, 68% (13) had OS and 32% (6) did not ($p=0.80$). Inter-group comparisons between compliant and noncompliant showed no significant differences and between OS and nonOS groups, the nonOS group started with larger nasolabial angles at T1 ($p<0.05$). At T2, there were no significant cephalometric differences between both group sets. At T3, compliant patients showed significantly more upper incisor proclination than noncompliant patients. Between OS and nonOS groups, the OS group had significantly decreased ANB, Wits, convexity, and overjet, as well as deeper FMA and larger nasolabial angles at T3 ($p<0.05$).

Conclusions: Patients compliant with PHG showed no difference in the need for OS compared with those that were not. Compliance with PHG did not create any significant differences, however, after comprehensive orthodontic treatment, compliant patients showed more

upper incisor proclination and OS patients with decreased ANB, Wits, convexity, overjet, and FMA and larger nasolabial angles.

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Acknowledgements

I would like to acknowledge Doctor Lindsey Schuster and her staff for their excellent care in the Cleft-Craniofacial Center at Children's Hospital of Pittsburgh. Their support in ensuring all resources were available throughout this project is greatly appreciated. Additionally, Doctor Schuster's leadership and guidance in the project has been paramount, and the time and effort she shared to ensure the project's progression has made this possible. I would like to acknowledge Doctor Nilesh Shah for his expertise and patience in discussing and clarifying proper statistical methods and analyses. I would also like to acknowledge Doctor Joseph Petrone for his guidance on this project.

Nomenclature

ABG	Alveolar bone graft
ANB	A-point to Nasion to B-point
BCLP	Bilateral cleft lip and palate
CLP	Cleft lip and palate
CP	Cleft palate
CVM(S)	Cervical vertebral maturation (stage)
FH	Frankfort horizontal
FMA	Frankfort mandibular angle
Gn	Gnathion
Go	Gonion
IMPA	Incisor mandibular plane angle
L1-NB	Lower incisor to Nasion and B-point
LFH	Lower face height
MPA	Mandibular plane angle
NAM	Nasoalveolar moulding
NLA	Nasolabial angle
OS	Orthognathic surgery
PFH	Posterior facial height
PHG	Protraction headgear
PSIO	Pre-surgical infant orthopedics

SN-GoGn	Sella and Nasion to Gonion and Gnathion
SNA	Sella to Nasion to A-point
SNB	Sella to Nasion to B-point
T1	Initial
T2	Post-protraction headgear
T3	Post-orthodontic treatment
U1-FH	Upper central incisor to Frankfort horizontal
U1-NA	Upper central incisor to Nasion and A-point
U1-SN	Upper central incisor to Sella and Nasion
UCLP	Unilateral cleft lip and palate
UFH	Upper face height
UPMC	University of Pittsburgh Medical Center

1.0 Background

Cleft lip and palate (CLP) are common congenital differences attributed to disturbances during embryological development that affect approximately 1 in 600 births in the United States (ACPA 2014). Approximately 10% to 15% of cleft lips and 40% to 50% of cleft palates are associated with syndromes (ACPA 2001). Nonsyndromic clefts may occur due to multifactorial inheritance, teratogen exposure, or spontaneously (ACPA 2001, Proffit 2013). Germ layers and formation of the neural tube begin to form within the first few weeks of life followed with continued cell proliferation to form pharyngeal arch predecessors to head and neck structures. The tongue begins to form during the fourth week with concurrent development of the facial prominences. The face develops from the frontonasal and paired maxillary and mandibular prominences as well as the subsequent development of medial and lateral nasal processes. Fusion of the medial nasal process and maxillary prominences provide continuity of the upper lip, fusion of medial nasal processes during the sixth week form the primary palate, and fusion of palatine shelves of the maxillary prominences with the inferior movement of the tongue help to form the secondary palate the following week. Failure of fusion results in a cleft (Enlow 2008).

1.1 Cleft lip and palate and midfacial retrusion

It is common for patients with cleft lip and palate to develop maxillary hypoplasia, resulting in a class III skeletal relationship and negative overjet. The etiology may be associated with intrinsic deficiencies, functional muscle distortions, and iatrogenic factors (Ross 1987). Numerous

studies on adults with unoperated clefts have shown minimal deviations from adults without clefts (Ross 1969, Han 1995) implicating that iatrogenic factors introduced during treatment may be a significant source of midface deficiency in patients with CLP (Ross 1987).

Children with CLP begin their care at birth with a craniofacial team and families receive instruction on proper feeding techniques. Pre-surgical infant orthopedic (PSIO) appliances, such as extraoral taping or nasoalveolar moulding (NAM) appliances, may be used to help approximate maxillary segments prior to lip revision. In addition to preparing the segments, NAM may improve nasal symmetry and help to lengthen the columella (Shi 2015). Within the first few months, surgical repair of the lip is complete followed with surgical repair of the palate around six and eighteen months of age (ACPA 2018).

For patients with unilateral cleft lip and palate (UCLP), surgical lip repair within the first six months of life has no appreciable adverse effects on growth of the maxillary size and position (Ross 1969, Shetye 2004, Liao 2005). However, surgical palate repair has been suggested to have inhibitory effects on the growing maxilla. This intervention creates scar formation that inhibits maxillary growth (Naqvi 2015, Ross 1969, Russell 2011, Shetye 2004, Susami 2014). Specifically, the scar tissue may inhibit separation of the maxilla, palatine, and pterygoid plates, thereby creating a form of maxillary ankylosis (Ross 1969). Additionally, aggressive palatoplasty may leave an area of denuded bone adjacent to the alveolus upon which periodontal fibers may become embedded, contracting and collapsing the arches as well as possibly disrupting vertical eruption of the dentition (Ross 1969, Ross 1987). Palatoplasties for UCLP repair have been associated with increased rate of midfacial retrusion observed between 8 and 15-years of age, especially if the surgery was completed prior to the first year of life (Susami 2014, Shi 2015). Impaired maxillary growth subsequently leads to a retrognathic maxilla, flatter midface, more concave profile,

distortion of dentoalveolar structures, and difference in posture and shape of the mandible that may increase the mandibular plane angle and decrease protrusion of the chin as the child ages (Ross 1969, Russell 201, Semb 2005,). This is in contrast to those with unoperated unilateral cleft lip and palate showing SNA to be normal or prognathic compared to patients without clefts (Shetye 2004); specifically, those without surgical palatal repair had potential for adequate maxillary growth and occlusion capable of compensating for the skeletal discrepancy (Ross 1969, Mars 1990, Filho 1996).

Afterwards, patients receive periodic evaluations and treatment to ensure proper development of hearing, speech, dentition, and psychosocial wellbeing. Orthodontic evaluation commonly occurs in early mixed dentition for Phase I to prepare the child for an alveolar bone graft (ABG). ABG occurs at approximately ages 9 to 11 or coincides with one to two-thirds root formation of the permanent maxillary canines to provide an eruption path through bone (Shi 2015). Treatment for Phase II orthodontics are considered in permanent dentition with evaluation and consultation for orthognathic surgery after completion of growth.

1.2 Protraction headgear

There are several treatment options to address midfacial retrusion that are often dependent upon severity and physical maturity of the patient. Orthopedic appliances such as the chin cup, Frankel III, and protraction headgear (PHG) or procedures such as maxillary distraction osteogenesis or bone-anchored protraction may be used to alleviate skeletal Class III discrepancies (Richardson 2018, Westwood 2003).

PHG is a functional orthodontic appliance often used in prepubertal children in early to late mixed dentition, particularly before age 10, to treat maxillary deficiency in skeletal Class III discrepancies (Kim 1999). This treatment aims to displace the maxilla forward into a skeletal and dental Class I relationship with positive overjet. Mandibular downward and backward rotation also occurs. Cephalometric changes that have been observed with PHG treatment in patients without CLP are increases in SNA, Wits, ANB, mandibular plane, and upper incisor angulation, decreases in SNB, IMPA and palatal plane values, and forward movement of Point A (Cordasco 2014, Foersch 2015, Kim 1999). Long-term follow-up studies re-assessing patients after their pubertal growth spurt, however, suggested that treatment effects in SNA, SNB, ANB, and skeletal effects were not maintained (Mandall 2016). PHG may have better prognosis to reach Class I relationships with positive overjet in patients that are younger than age 10 with shorter ramus, obtuse cranial base angle, and lower mandibular plane angle (Baccetti 2004, Wells, 2006) or to overcorrect until overjet is 5 to 8 mm and the molars are in Class II (Westwood 2003). PHG in patients with CLP has demonstrated maxillary protraction and clockwise mandibular rotation in prepubertal patients and improves both cephalometric hard and soft tissue values (Dogan 2012, Kobayashi 2013, Richardson 2018, Hoefert 2010, Susami 2014). Long-term prognosis, however, showed large variation of relapse (Susami 2014). Treating Class III discrepancies in patients with CLP is difficult because results may depend more on surgical history than the orthopedic appliance (Delaire 1997); specifically, effects of protraction may vary cleft to cleft, especially the amount and condition of the palatal scar tissue (Friede 1981, Susami 2014, Tindlund 1993).

In patients without CLP, relapse rates range from approximately 12% to 33% where negative overjet has been observed in patients that have completed growth with history of PHG therapy (Baccetti 2004, Mandall 2016, Nardoni 2015, Wells 2009). PHG starting between the ages

of 7 to 9 yielded patients that maintained positive overjet by age 15, thus odds of needing orthognathic surgery were 3.5 times more likely when PHG was not used compared to those had early PHG therapy (Mandall 2016). There is little evidence suggesting long-term prognosis of PHG therapy in patients with CLP and its prognostic factor in predicting whether early measures of successful PHG therapy correlates with a decreased incidence of orthognathic surgery.

2.0 Purpose of the present study

The aim of this study is to assess the need for orthognathic surgery (OS) and the relationship with compliance in PHG therapy. The secondary aim is to evaluate cephalometric characteristics of patients that did not need OS and to increase the available long-term data on the use of PHG in patients with CLP.

3.0 Materials and Methods

3.1 Inclusion criteria

The Institutional Review Board at the University of Pittsburgh Medical Center (UPMC) approved this study. 23 participants for this study were selected from the UPMC Children's' Hospital of Pittsburgh craniofacial center with the following inclusion criteria: (1) Patients with nonsyndromic (2) unilateral or bilateral cleft lip and palate treated with (3) PHG therapy with or without expansion followed by (4) completion of Phase II orthodontics. Patients would have history of (5) cleft lip repair (6) cleft palate. Additionally, patients selected would have (7) a minimum of three lateral cephalograms at pre-PHG (T1), post-PHG (T2), and pre-surgical or post-orthodontic treatment (T3) of at least age 15 for females and 17 for males. The exclusion criteria were patients that had (1) syndromic clefts or (2) did not receive PHG, (3) or lacking lateral cephalograms at designated timepoints.

3.2 Orthodontic treatment

Variations of bonded, banded, or quad-helix palatal expanders were used if arch form coordination was needed prior to protraction. Buccal arms from the permanent first molars were extended to the canine area. Protraction was applied with PHG and 170-gram elastics were connected to each buccal hook and directed slightly downward in relation to the occlusal plane. Patients were instructed to wear the headgear for at least 12 hours a day until at least 3 mm of

positive overjet was achieved. Comprehensive orthodontic treatment was completed after protraction.

3.3 Measurements

Cephalograms were produced before and after PHG therapy and another representing completion of growth at age 15 for females and 17 for females or as a part of the patient's pre-surgical records. Patients records were reviewed and the presence or absence of an expander, comments on PHG therapy compliance, and the presence or absence or recommendation for orthognathic surgery were recorded. Cephalograms were digitized and traced using Dolphin Imaging and Management Solutions to assess the variables shown in Figure 1 and Table 1. 25 cephalograms were re-traced to evaluate intra-rater reliability.

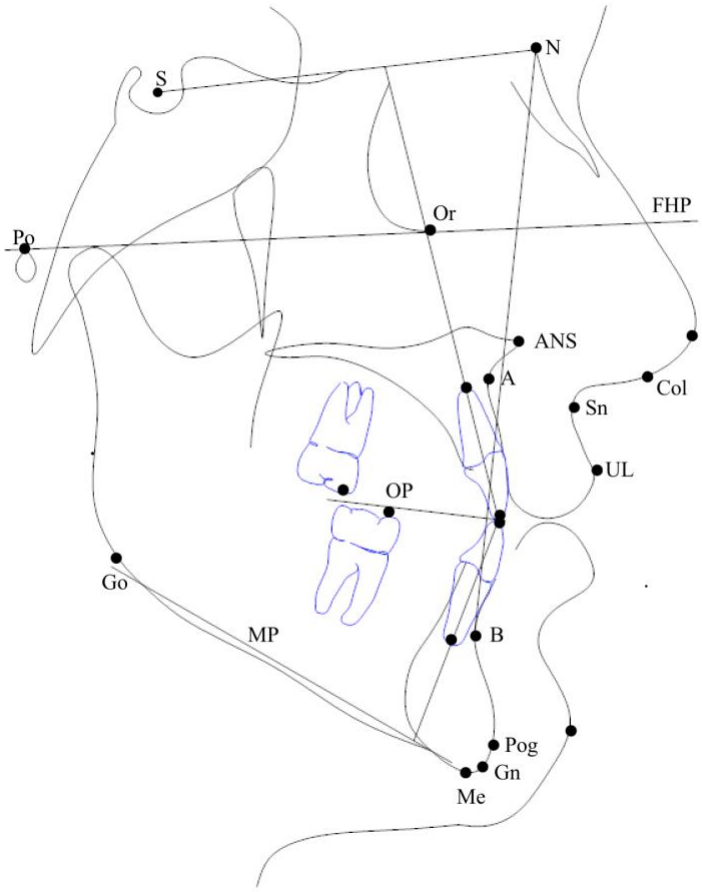

Figure 1 Cephalometric tracing.

S = sella; N = nasion; Po = porion; Or = orbitale; ANS = anterior nasal spine; A = point A; B = point B; Pog = pogonion; Gn = Gnathion; Me = menton; Go = gonion; Col = columella; Sn = subnasale; UL = upper lip; MP = mandibular plane (Go-Gn); OP = occlusal plane; FHP = Frankfort horizontal plane (Po-Or).

Table 1 Cephalometric measurements.

Reference angles and lengths used to objectively evaluate skeletal, dental, and soft tissue parameters.

Skeletal A-P	Dental
SNA (°)	U1-SN (°)
SNB (°)	U1-FH (°)

ANB (°)

Convexity (NA-APo) (°)

Wits Appraisal (mm)

U1-NA (°)

U1-NA (mm)

L1-OP (°)

IMPA (L1-MP) (°)

L1-NB (°)

L1-NB (mm)

Interincisal Angle (U1-L1) (°)

Overbite (mm)

Overjet (mm)

Skeletal Vertical

Upper Face Height (N-ANS) (mm)

Lower Face Height (ANS-Me) (mm)

UFH/TFH (N-ANS:N-Me) (%)

LFH/TFH (ANS-Me:N-Me) (%)

Soft Tissue

Upper Lip to E-Plane (mm)

Lower Lip to E-Plane (mm)

Nasolabial Angle (Col-Sn-UL) (°)

Mandibular/Occlusal Plane

SN-GoGn (°)

FMA (MP-FH) (°)

OP-FH (°)

3.4 Statistical analyses

Chi-square test was used to evaluate the association between compliance in PHG therapy and the presence or recommendation for OS. Two-sample independent t-tests were used to evaluate significant differences between compliant and noncompliant groups and OS and nonOS groups at T1, T2, and T3. Two-sample paired t-tests were used to evaluate significant changes among patients in the compliant, noncompliant, OS, and nonOS groups.

4.0 Results

23 patients matched the inclusion criteria for this study and are described in Table 2. 10 (43%) females and 13 (57%) of the 23 are males with 18 (78%) with complete UCLP and 5 (22%) of 23 with complete BCLP. The average age at T1 was 8.3 years, T2 was 9.5 years, and T3 was 16.7 years and the average PHG treatment duration was 7.4 months.

Table 2 Patient distribution.

23 patients were included in this study; majority of the sample were males with complete UCLP. Average age of patients starting PHG was 8.3 years.

Gender	*Expansion*	*Cleft type*	*Age*										*n*
			6	*6.5*	*7*	*7.5*	*8*	*8.5*	*9*	*9.5*	*10*	*10.5*	
Female	Yes	UCLP					2	2	3			1	8
		BCLP				1							1
	No	UCLP											
		BCLP										1	1
Male	Yes	UCLP			1	1		2		1	1		6
		BCLP					1	1					2
	No	UCLP				1		2		1			4
		BCLP						1					1
Total					1	3	3	8	3	2	1	2	23

19 (83%) of 23 patients reported compliance with PHG therapy. Among those that were compliant, 68% had OS and 32% did not. 4 (17%) patients were not compliant with PHG and 75% needed OS. There was no significant association between PHG compliance and OS (Table 3).

Table 3 Pearson Chi-square test for association between PHG compliance and OS.

There is no signficant assocaition between PGH compliance and OS. Significance: * p < 0.05.

		Surgery		Total
		No	Yes	
Compliance	No	1 (25%)	3 (75%)	4 (17%)

Yes	6 (32%)	13 (68%)	19 (83%)
Total	7	16	23

P-value = 0.80

At T1, compliant and noncompliant patients had no significant cephalometric differences. The OS group at T1 had an average nasolabial angle of 102.1°, 18.2° flatter than the nonOS group (Table 4).

Table 4 Average cephalometric values at T1.

Compliant and noncompliant groups were relatively similar; however, patients that ended up not receiving OS, the upper lip was further behind and nasolabial angle was more obtuse at T1. Signficance: * p < 0.05.

	Compliant	Noncompliant	P	OS	NonOS	P
SNA (°)	78.6	80.2	0.52	79.5	77.4	0.31
SNB (°)	77.7	76.4	0.58	78.3	75.5	0.16
ANB (°)	0.8	3.8	0.10	1.2	1.8	0.67
Convexity (°)	0.1	7.9	0.06	1.1	2.3	0.74
Wits (mm)	-1.5	0.0	0.45	-1.2	-1.4	0.87
UFH (mm)	42.5	40.5	0.21	42.0	42.6	0.66
LFH (mm)	55.8	54.9	0.64	55.6	55.7	0.92
UFH/TFH (%)	44.5	44.0	0.71	44.3	44.6	0.81
LFH/TFH (%)	55.5	56.0	0.71	55.7	55.4	0.80
SN-GoGn (°)	33.9	37.7	0.19	33.5	37.0	0.14
FMA (°)	28.3	30.7	0.31	28.1	30.1	0.31
OP-FH (°)	8.1	10.1	0.50	8.0	9.3	0.61
U1-SN (°)	80.3	77.9	0.79	80.6	78.2	0.74
U1-FH (°)	87.9	86.4	0.87	87.6	87.8	0.98
U1-NA (°)	1.7	-2.3	0.65	1.1	0.8	0.97
U1-NA (mm)	-3.4	-3.9	0.81	-3.3	-3.9	0.73
L1-OP (°)	73.8	77.4	0.28	74.4	74.7	0.92
IMPA (°)	86.0	82.0	0.35	85.6	84.5	0.76
L1-NB (°)	19.6	17.6	0.61	19.0	19.8	0.80
L1-NB (mm)	2.7	2.9	0.88	3.0	2.2	0.39
Interincisal Angle (°)	157.9	160.9	0.35	158.8	157.6	0.89
Overbite (mm)	-0.5	-0.3	0.89	-0.3	-0.9	0.74
Overjet (mm)	-5.2	-2.7	0.17	-5.1	-4.2	0.60
Upper Lip to E-Plane (mm)	-3.7	-3.3	0.86	-3.0	-5.1	0.24
Lower Lip to E-Plane (mm)	0.4	1.2	0.70	1.4	-1.4	0.09
Nasolabial Angle (°)	103.8	125.5	0.05	102.1	120.2	0.04*

At T2, compliant patients had 11.0°, 10.6°, and 11.2° more proclination at U1-SN, U1-FH, and U1-NA, respectively, and 3.6 mm more upper incisor and 2.1 mm more upper lip protrusion when compared to noncompliant patients though statistically insignificant. Compliant patients had 1.9 mm of overjet, 3.9 mm more than noncompliant patients at T2 that approached significance (Table 5).

Table 5 Average cephalometric values at T2.

No statistically significant differences between groups. Signifciance: * p < 0.05.

	Compliant	Noncompliant	P	OS	NonOS	P
SNA (°)	80.7	80.9	0.96	80.9	80.3	0.80
SNB (°)	75.7	76.6	0.75	76.5	74.5	0.37
ANB (°)	5.0	4.3	0.75	4.4	5.9	0.39
Convexity (°)	8.1	7.6	0.90	7.3	9.6	0.51
Wits (mm)	2.9	2.0	0.67	2.4	3.4	0.54
UFH (mm)	43.3	44.8	0.69	43.5	43.7	0.97
LFH (mm)	59.4	59.1	0.94	59.0	60.1	0.74
UFH/TFH (%)	43.8	44.4	0.74	44.1	43.6	0.75
LFH/TFH (%)	56.2	55.6	0.74	55.9	56.4	0.75
SN-GoGn (°)	35.9	38.5	0.43	35.3	38.8	0.19
FMA (°)	29.5	31.7	0.44	29.8	30.1	0.89
OP-FH (°)	7.8	7.5	0.89	8.1	7.2	0.67
U1-SN (°)	89.1	78.1	0.20	86.1	89.6	0.63
U1-FH (°)	97.2	86.6	0.24	93.4	99.8	0.38
U1-NA (°)	8.4	-2.9	0.20	5.2	9.2	0.58
U1-NA (mm)	-1.5	-5.1	0.14	-1.9	-2.6	0.75
L1-OP (°)	75.7	79.1	0.20	76.3	76.3	1.00
IMPA (°)	82.6	76.8	0.07	81.9	80.7	0.66
L1-NB (°)	16.0	13.7	0.41	15.5	15.6	0.98
L1-NB (mm)	2.3	2.1	0.86	2.4	2.0	0.62
Interincisal Angle (°)	150.7	164.9	0.16	154.9	149.3	0.51
Overbite (mm)	0.2	1.9	0.15	0.6	0.3	0.83
Overjet (mm)	1.9	-2.0	0.09	0.8	2.4	0.40
Upper Lip to E-Plane (mm)	-2.0	-4.2	0.24	-2.1	-3.1	0.49
Lower Lip to E-Plane (mm)	1.6	1.5	0.93	2.3	-0.1	0.07
Nasolabial Angle (°)	109.4	114.5	0.58	106.5	118.9	0.09

At T3, upper incisors are significantly more proclined in the compliant group compared to the noncompliant group. Specifically, compliant patients had 18.2°, 18.0°, and 19.6° more proclination at U1-SN, U1-FH, and U1-NA, respectively, than noncompliant patients. In patients that needed OS, ANB was 5.8° and Wits 6.3 mm smaller, 10.5° more concave, overjet 9.5 mm more negative, and FMA was 5.3° deeper. OS patients also had flatter nasolabial angles (Table 6).

Table 6 Average cephalometric values at T3.

Compliant patients had more proclined incisors than noncompliant patients. OS patients were more skeletal and dental Class III and deep than nonOS patients. Signifciance: * p < 0.05

	Compliant	Noncompliant	P	OS	NonOS	P
SNA (°)	75.3	76.7	0.59	74.9	77.1	0.28
SNB (°)	80.7	78.3	0.34	81.4	77.9	0.08
ANB (°)	-5.4	-1.7	0.20	-6.5	-0.7	0.01*
Convexity (°)	-14.6	-4.1	0.10	-16.0	-5.5	0.04*
Wits (mm)	-7.1	-4.7	0.42	-8.6	-2.3	0.01*
UFH (mm)	52.5	48.7	0.54	53.6	47.8	0.27
LFH (mm)	68.8	69.6	0.92	69.7	67.3	0.70
UFH/TFH (%)	43.4	41.9	0.33	43.6	42.2	0.26
LFH/TFH (%)	56.6	58.1	0.33	56.4	57.8	0.26
SN-GoGn (°)	31.1	36.9	0.10	30.9	35.0	0.15
FMA (°)	26.6	32.8	0.09	26.1	31.3	0.01*
OP-FH (°)	4.5	8.1	0.32	3.5	8.8	0.06
U1-SN (°)	103.8	85.6	0.01*	99.0	104.4	0.36
U1-FH (°)	110.8	92.8	0.00*	106.7	109.9	0.56
U1-NA (°)	28.5	8.9	0.01*	24.2	27.2	0.63
U1-NA (mm)	6.0	1.0	0.05	4.8	6.0	0.57
L1-OP (°)	75.6	76.2	0.88	75.8	75.6	0.96
IMPA (°)	82.3	79.0	0.52	81.6	81.9	0.95
L1-NB (°)	16.6	17.4	0.88	16.8	16.6	0.06
L1-NB (mm)	2.9	4.1	0.46	3.3	2.6	0.63
Interincisal Angle (°)	140.3	155.4	0.07	145.6	136.9	0.21
Overbite (mm)	0.9	2.6	0.37	2.0	-0.5	0.09
Overjet (mm)	-4.0	-5.7	0.59	-7.2	2.3	0.00*
Upper Lip to E-Plane (mm)	-10.0	-6.6	0.15	-9.4	-9.5	0.96
Lower Lip to E-Plane (mm)	0.0	-0.2	0.95	1.1	-2.7	0.05
Nasolabial Angle (°)	93.2	104.0	0.35	95.7	93.6	0.02*

Changes among patients that were compliant with headgear are described in Table 7. From T1 to T2, patients that were compliant showed significant improvements in SNA, SNB, ANB, convexity, Wits, and overjet after PHG therapy. Upper incisors proclined 8.8°, 9.3°, and 6.7° in U1-SN, U1-FH, and U1-NA, respectively, and protruded 1.9 mm with 3.4° and 3.6° of lower incisor retroclination in IMPA and L1-NB, respectively, corresponding to 7.2° decrease in interincisal angle. Upper lip came forward 1.7 mm and SN-GoGn opened 2.0°. From T2 to T3, unfavorable changes in SNA, SNB, ANB, convexity, Wits, and overjet occurred. Upper incisors proclined 14.7°, 13.6°, and 20.2° more in U1-SN, U1-FH, and U1-NA, respectively, and protruded 7.5 mm corresponding to 10.4° further decrease in interincisal angle. Upper lip went back 8.0 mm, nasolabial angle flattened 16.2°, and mandibular planes rotated counterclockwise. Overall, compliant patients from T1 to T3 showed 3.3° of SNA backwards, 3.0° of SNB forwards with decreases of 6.2° in ANB, 14.7° in convexity, and 5.6 mm in Wits. Absolute values of UFH and LFH increased, but ratios compared to TFH did not change. Upper incisors proclined 23.5°, 22.9°, and 26.8° in U1-SN, U1-FH, and U1-NA, respectively, 9.4 mm protrusion with 3.7° retroclination in IMPA corresponding to 17.6° decrease in interincisal angle. Upper lip retruded 6.3 mm and SN-GoGn opened 2.8°. Overjet increased from -5.2 to -4.0 mm was not significant.

Table 7 Changes in patients compliant with PHG therapy.

Patients that were compliant with PHG therapy observed favorable changes in AP dimension after PHG with upper incisor proclination and protrusion, lower incisor retroclination and retrusion, and clockwise rotation of the mandible with PHG. During fixed appliances, improvements relapsed with unfavorable AP changes. Facial heights increased, upper incisors continued to procline and mandible rotated counterclockwise. Overall, compliant patient became more Class III attributable to combination of maixllary retrusion and mandibular prognathism, MPA deepened, upper incisors proclined and protruded, lower incisor retroclined, and upper lip became further retruded with no signficant changes in overjet. Signficance: $p < 0.05$.

	T2-T1	P	T3-T2	P	T3-T1	P
SNA (°)	2.2	0.01*	-5.4	0.00*	-3.3	0.00*
SNB (°)	-2.0	0.00*	5.0	0.00*	3.0	0.00*
ANB (°)	4.1	0.00*	-10.4	0.00*	-6.2	0.00*
Convexity (°)	8.0	0.00*	-22.7	0.00*	-14.7	0.00*
Wits (mm)	4.4	0.00*	-10.0	0.00*	-5.6	0.00*
UFH (mm)	0.8	0.59	9.1	0.01*	10.0	0.00*
LFH (mm)	3.6	0.06	9.5	0.02*	13.0	0.00*
UFH/TFH (%)	-0.7	0.28	-0.4	0.48	-1.1	0.09
LFH/TFH (%)	0.7	0.28	0.4	0.48	1.1	0.09
SN-GoGn (°)	2.0	0.00*	-4.8	0.00*	-2.8	0.00*
FMA (°)	1.3	0.17	-2.9	0.03*	-1.7	0.14
OP-FH (°)	-0.2	0.79	-3.4	0.05	-3.6	0.05
U1-SN (°)	8.8	0.00*	14.7	0.00*	23.5	0.00*
U1-FH (°)	9.3	0.00*	13.6	0.01*	22.9	0.00*
U1-NA (°)	6.7	0.00*	20.2	0.00*	26.8	0.00*
U1-NA (mm)	1.9	0.00*	7.5	0.00*	9.4	0.00*
L1-OP (°)	1.9	0.12	-0.2	0.93	1.7	0.27
IMPA (°)	-3.4	0.02*	-0.3	0.86	-3.7	0.01*
L1-NB (°)	-3.6	0.01*	0.7	0.72	-2.9	0.06
L1-NB (mm)	-0.4	0.23	0.6	0.20	0.1	0.75
Interincisal Angle (°)	-7.2	0.01*	-10.4	0.02*	-17.6	0.00*
Overbite (mm)	0.7	0.39	0.8	0.36	1.5	0.16
Overjet (mm)	7.2	0.00*	-5.9	0.00*	1.2	0.35
Upper Lip to E-Plane (mm)	1.7	0.04*	-8.0	0.00*	-6.3	0.00*
Lower Lip to E-Plane (mm)	1.3	0.11	-1.6	0.02*	-0.4	0.64
Nasolabial Angle (°)	5.6	0.29	-16.2	0.00*	-10.6	0.12

Changes among patients that were not compliant with headgear are described in Table 8. From T1 to T2, L1-NB retruded 0.8 mm with no other significant changes. From T2 to T3, significant unfavorable changes occurred in ANB, Wits, convexity, and overjet. Upper incisors protruded 6.1 mm. Overall, noncompliant patients had 12.0° decrease in convexity and 14.7 mm of absolute increase in LFH. SNA and ANB decreases of 3.5° and 5.5°, respectively, approached significance.

Table 8 Changes in patients not compliant with PHG therapy.

Patients not compliant with PGH therapy showed only 0.8 mm lower incisor retrusion from T1 to T2. During fixed appliances, upper incisors protruded 6.1 mm and unfavorable changes seen in ANB, convexity, Wits, and overjet. Overall, LFH increased and patient became more concave. Significance: $p < 0.05$.

	T2-T1	P	T3-T2	P	T3-T1	P
SNA (°)	0.7	0.73	-4.2	0.13	-3.5	0.05
SNB (°)	0.2	0.90	1.7	0.24	1.9	0.07
ANB (°)	0.5	0.55	-6.0	0.01*	-5.5	0.05
Convexity (°)	-0.3	0.81	-11.7	0.02*	-12.0	0.04*
Wits (mm)	2.0	0.32	-6.8	0.02*	-4.8	0.19
UFH (mm)	4.3	0.21	3.9	0.37	8.2	0.08
LFH (mm)	4.1	0.09	10.6	0.10	14.7	0.03*
UFH/TFH (%)	0.5	0.76	-2.5	0.07	-2.1	0.27
LFH/TFH (%)	-0.5	0.76	2.5	0.07	2.1	0.27
SN-GoGn (°)	0.7	0.71	-1.6	0.37	-0.9	0.53
FMA (°)	1.0	0.66	1.1	0.71	2.1	0.41
OP-FH (°)	-2.6	0.48	0.5	0.86	-2.0	0.58
U1-SN (°)	0.1	0.99	7.6	0.11	7.7	0.31
U1-FH (°)	0.2	0.98	6.2	0.24	6.4	0.28
U1-NA (°)	-0.6	0.94	11.8	0.10	11.2	0.14
U1-NA (mm)	-1.2	0.70	6.1	0.03*	4.8	0.18
L1-OP (°)	1.7	0.55	-2.8	0.48	-1.2	0.81
IMPA (°)	-5.2	0.22	2.2	0.59	-3.0	0.57
L1-NB (°)	-3.9	0.31	3.7	0.42	-0.2	0.97
L1-NB (mm)	-0.8	0.01*	2.0	0.26	1.2	0.45
Interincisal Angle (°)	4.0	0.72	-9.5	0.29	-5.5	0.66
Overbite (mm)	2.2	0.07	0.7	0.75	2.9	0.18
Overjet (mm)	0.7	0.82	-3.8	0.02*	-3.0	0.48
Upper Lip to E-Plane (mm)	-0.8	0.40	-2.5	0.10	-3.3	0.08
Lower Lip to E-Plane (mm)	0.3	0.73	-1.6	0.34	-1.3	0.52
Nasolabial Angle (°)	-11.0	0.13	-10.6	0.34	-21.5	0.07

Changes in patients that needed OS are shown in Table 9. From T1 to T2, SNB went back 1.8° and ANB improved 3.3°. Convexity increased 6.2°, Wits increased 3.6 mm, and overjet increased 5.8 mm. Sn-GoGn rotated clockwise 1.8°, upper incisors proclined 5.5° at U1-SN and lower incisors retroclined 3.7° and 3.4 at IMPA and L1-NB, respectively. From T2 to T3, relapse was evident and unfavorable changes occurred. SNA retruded 6.1°, SNB protruded 4.9°, and ANB decreased 10.9°. Wits decreased 11.0 mm, overjet decreased 7.9 mm, and patient became 23.3° more concave. Facial heights increased while maintaining similar ratios to TFH and mandibular and occlusal planes rotated counterclockwise. Upper incisors proclined 12.9°, 13.3°, and 19.0° at U1-SN, U1-FH, and U1-NA, respectively and protruded 6.7 mm with 9.3° decrease in interincisal angle. Upper lip retruded 7.3 mm and nasolabial angle became 10.8° flatter. Overall, SNA

decreased 4.6°, SNB increased 3.0°, and ANB decreased 7.7°. Convexity and Wits decreased 17.1° and 7.4 mm, respectively. Upper face height increased 11.6 mm and lower 14.1 mm with no changes in their relationship with TFH. SN-GoGn rotated 2.7° and occlusal plane rotated 4.6° counterclockwise. Upper incisors proclined 18.4°, 19.2°, and 23.1° at U1-SN, U1-FH, and U1-NA, respectively, and protruded 8.1 mm and IMPA retraced 4.0° with 13.2° steepening of interincisal angle. Upper lip retruded 6.4 mm. No significant changes in overjet observed overall.

Table 9 Changes in patients that needed OS.

OS patients showed favorable changes in AP, proclined upper (less than nonOS) and retroclined lower incisors, and slight opening of MPA and retrusion of lower incisors with PHG. During fixed appliances, OS patients showed unfavorable relapse in AP measurements, anterior facial heights increased, MPA deepend, and upper incisors proclined and protruded further. Overall, OS patients became more Class III attributable to combination of maxillary retrusion and mandibular prognathism, MPA deepend, upper incisors proclined and lowers retroclined, and upper lip became further retruded. Significance: $p < 0.05$.

	T2-T1	P	T3-T2	P	T3-T1	P
SNA (°)	1.4	0.10	-6.1	0.00*	-4.6	0.00*
SNB (°)	-1.8	0.01*	4.9	0.00*	3.0	0.00*
ANB (°)	3.3	0.00*	-10.9	0.00*	-7.7	0.00*
Convexity (°)	6.2	0.00*	-23.3	0.00*	-17.1	0.00*
Wits (mm)	3.6	0.00*	-11.0	0.00*	-7.4	0.00*
UFH (mm)	1.6	0.43	10.0	0.01*	11.6	0.00*
LFH (mm)	3.4	0.13	10.7	0.02*	14.1	0.00*
UFH/TFH (%)	-0.2	0.74	-0.5	0.44	-0.7	0.31
LFH/TFH (%)	0.3	0.74	0.5	0.44	0.4	0.31
SN-GoGn (°)	1.8	0.03*	-4.4	0.00*	-2.7	0.00*
FMA (°)	1.8	0.12	-3.7	0.01*	-2.0	0.08
OP-FH (°)	0.0	0.98	-4.6	0.01*	-4.6	0.01*
U1-SN (°)	5.5	0.04*	12.9	0.00*	18.4	0.00*
U1-FH (°)	5.9	0.06	13.3	0.00*	19.2	0.00*
U1-NA (°)	4.1	0.16	19.0	0.00*	23.1	0.00*
U1-NA (mm)	1.4	0.18	6.7	0.00*	8.1	0.00*
L1-OP (°)	2.0	0.17	-0.6	0.78	1.4	0.45
IMPA (°)	-3.7	0.03*	-0.3	0.87	-4.0	0.02*
L1-NB (°)	-3.4	0.03*	1.3	0.55	-2.2	0.17
L1-NB (mm)	-0.6	0.14	0.9	0.14	0.3	0.61
Interincisal Angle (°)	-3.9	0.30	-9.3	0.03*	-13.2	0.01*
Overbite (mm)	0.9	0.37	1.4	0.10	2.3	0.05

Overjet (mm)	5.8	0.00*	-7.9	0.00*	-2.1	0.10
Upper Lip to E-Plane (mm)	0.9	0.34	-7.3	0.00*	-6.4	0.00*
Lower Lip to E-Plane (mm)	1.0	0.24	-1.2	0.10	-0.2	0.79
Nasolabial Angle (°)	4.5	0.44	-10.8	0.01*	-6.3	0.39

Changes in patients that did not need OS are shown in Table 10. From T1 to T2, favorable changes were observed in SNA, SNB, ANB, Wits, and convexity, upper incisors proclined 11.4°, 12.0°, and 8.4° at U1-SN, U1-FH, and U1-NA, respectively, and lower incisors retroclined 4.2° at L1-NB. Overjet increased 6.6 mm, upper lip moved forward 2.0 mm, and LFH increased 4.4 mm. From T2 to T3, SNB, ANB, Wits, and convexity changed unfavorably, Sn-GoGn rotated 3.7° counterclockwise, upper incisors protruded 8.6 mm, upper lips retracted 6.4 mm, and nasolabial angle became 25.3° more acute. Additionally, UFH and LFH increased 4.2 and 7.2 mm, respectively, with no significant differences in their ratios to TFH. Overall, SNB increased 2.3° and ANB convexity decreased 2.6° and 7.8°, respectively. Upper incisors proclined 26.2° and 26.4° at U1-SN and U1-FH, respectively, and protruded 9.9 mm at U1-NA and overjet increased 6.5 mm. Upper lip retruded 4.4 mm, nasolabial angle decreased 26.7°, and UFH and LFH increased 5.3 and 11.6 mm, respectively, with UFH/TFH decreasing 2.4% and LFH/TFH increasing 2.4%.

Table 10 Changes in patients that did not need OS.

Patients that did not need OS showed favorable changes in AP, proclined upper incisors, and slight opening of MPA and retrusion of lower incisors with PHG. During fixed appliances, there was unfavorable relapse in AP measurements, anterior facial heights increased, SN-GoGn deepend, upper incisors protruded, and nasolabial angle became more acute. Overall, SNB came forward and AP measurements indicate increases in Class III and absolute UFH and LFH increases with an increased LFH/TFH ratio. Upper incisors proclined and protruded with 6.5 mm increase in overjet, and upper lip became more acute. Significance: $p < 0.05$.

	T2-T1	P	T3-T2	P	T3-T1	P
SNA (°)	3.0	0.01*	-3.2	0.05	-0.2	0.80
SNB (°)	-1.1	0.02*	3.4	0.01*	2.3	0.03*

ANB (°)	4.0	0.00*	-6.6	0.00*	-2.6	0.03*
Convexity (°)	7.3	0.00*	-15.1	0.00*	-7.8	0.01*
Wits (mm)	4.9	0.00*	-5.8	0.00*	-0.9	0.47
UFH (mm)	1.1	0.16	4.2	0.03*	5.3	0.00*
LFH (mm)	4.4	0.00*	7.2	0.00*	11.6	0.00*
UFH/TFH (%)	-1.0	0.15	-1.5	0.19	-2.4	0.02*
LFH/TFH (%)	1.0	0.15	1.5	0.19	2.4	0.02*
SN-GoGn (°)	1.8	0.03*	-3.7	0.01*	-2.0	0.09
FMA (°)	0.0	0.98	1.2	0.51	1.2	0.57
OP-FH (°)	-2.1	0.09	1.6	0.55	-0.5	0.88
U1-SN (°)	11.4	0.01*	14.8	0.12	26.2	0.03*
U1-FH (°)	12.0	0.01*	10.1	0.29	22.1	0.07
U1-NA (°)	8.4	0.03*	18.0	0.07	26.4	0.03*
U1-NA (mm)	1.3	0.06	8.6	0.00*	9.9	0.00*
L1-OP (°)	1.7	0.31	-0.8	0.74	0.9	0.76
IMPA (°)	-3.8	0.12	1.2	0.65	-2.6	0.41
L1-NB (°)	-4.2	0.04*	1.01	0.73	-3.2	0.36
L1-NB (mm)	-0.3	0.52	0.7	0.35	0.4	0.56
Interincisal Angle (°)	-8.3	0.10	-12.4	0.13	-20.7	0.06
Overbite (mm)	1.2	0.24	-0.8	0.57	0.4	0.79
Overjet (mm)	6.6	0.00*	-0.1	0.96	6.5	0.00*
Upper Lip to E-Plane (mm)	2.0	0.04*	-6.4	0.00*	-4.4	0.01*
Lower Lip to E-Plane (mm)	1.4	0.26	-2.6	0.06	-1.2	0.40
Nasolabial Angle (°)	-1.3	0.87	-25.3	0.00*	-26.7	0.01*

5.0 Discussion

It is reported in the literature that short-term effects of PHG in patients without CLP younger than 10 years of age are ANB° +3.66°, SNA° +2.10, SNB -1.54°, and SN-GoGn +1.51; the maxilla is displaced anteriorly and rotated counterclockwise while the mandible is displaced posteriorly and rotated clockwise to improve the Class III (Cordasco 2014). In comparison with a study including patients with CLP, ANB +0.2°, SNA -0.1°, SNB -0.4°, overjet +4.3 mm, and overbite +1.7 mm was observed (Susami 2014). Overall, our patients with CLP experienced post-PHG changes of ANB +4.1°, SNA 2.2°, SNB -2.0°, SN-GoGn +2.0°, overjet + 7.2 mm, and overbite + 0.7 mm with counterclockwise rotation of the occlusal plane and clockwise rotation of the mandible. Compliant patients in our study exhibited short-term PHG changes more similarly to patients without clefts, however, this did not significantly alter the indication for orthognathic surgery when compared to noncompliant patients.

Post-pubertal treatment effects of PHG in patients without CLP are reported with 68 to 76% maintaining positive overjet 5.5 to 6 years post-treatment (Mandall 2016, Wells 2006, Westwood 2003). 25 to 33% relapse into negative overjet with exceeding pubertal mandibular growth (Wells 2006). Westwood et al suggests that though Class III characteristics may relapse post-treatment, 93% of skeletal changes that occurred prior to the pubertal growth spurt are maintained through skeletal maturity and no significant cephalometric changes were evident during that time (Westwood 2003). However, Mandall et al observed relapse in SNA, SNB, and ANB with no long-term skeletal effects from PHG aside from clockwise rotation of both the maxilla and mandible compared to untreated controls (Mandall 2016). In order to accommodate for possible resurgence of these Class III characteristics during growth, over-correction to an

overjet of 5 to 8 mm and Class II molar has been recommended (Westwood 2003). Nonetheless, the odds of needing surgery is 3.5 times more likely in untreated Class III patients without clefts compared to those treated with PHG (Mandall 2016). Among patients with CLP, Susami et al reports average post-pubertal decreases in SNA and ANB, increased MPA, and maintained overjet, however, the variation among the treatment effects were large and the prognosis is difficult to predict with Class III becoming severe during comprehensive treatment and nearly half of the patients needing orthognathic surgery (Susami 2014). Our patients experienced similar post-treatment changes. From T1 to T3, SNA retruded 3.3°, SNB protruded 2.8°, ANB decreased 6.1°, and overjet decreased 4.3 mm. 70% of our patients needed orthognathic surgery. Our study seems also reflects difficulty in assessing the prognosis for Class III growth among patients with CLP and did not reflect 68 to 76% of patients without CLP that maintained positive overjet post-puberty.

Treating Class III's are difficult in patients with CLP because results depend increasingly more on surgical repair of the clefts than orthopedic appliances (Delaire 1997). Fibrous scar tissue near palatine-maxillary suture may inhibit maxillary remodeling and anteroinferior direction of growth producing an abnormal growth process that the Class III profile becomes increasingly worse with age if no intervention is provided (Berkowitz 2015, Liao 2005, Naqvi 2015). Additionally, it is suggested that inhibited maxillary advancement may reduce nasal permeability and subsequent mouth-breathing in conjunction with adenoid hypertrophy that occurs in children may lead to forward positioning of the tongue, which represents an etiological factor in Class III malocclusions (Delaire 1997).

Certain characteristics may predispose patients without CLP to a favorable prognosis with PHG. Patients without CLP under age 10 or at stage 1 of cervical vertebral maturation (CVM) with decreased posterior facial height (PFH) and mandibular plane angle (MPA) and increased cranial

base angle, mandibular length, overbite, and LAFH may be cumulative indictors for post-pubertal maintenance of positive overjet (Baccetti 2004, Nardoni 2015, Wells 2006). Rather than orthopedic protraction of the PHG, it seems a major consideration for successful Class III treatment is the amount and direction of mandibular growth during adolescence (Wells 2006). Often, the maxilla is protracted down and forward with PHG as young patients with Class III's may exhibit a deficient maxilla in anteroposterior and vertical dimensions. The down and forward protraction rotate the mandible counterclockwise and this may be associated with increased late horizontal mandibular growth with subsequent relapse to negative overjet (Wells 2006). Patients with CLP exhibit deficient maxillae in all three dimensions and is further restricted with surgical scarring. In patients without operated clefts during infancy, the maxilla is near normal position as indicated by SNA (Naqvi 2015). Patients with unoperated clefts have been observed with increased gonial angles, possibly indicating a pattern of vertical mandibular growth, however in general, the growth of the mandible was similar among both operated and unoperated groups (Naqvi 2015). In our study, patients that did not need OS had an overall significant increase in LFH/TFH ratio from 55.4% at T1 to 57.8% at T3 while patients that did need OS did not have significant change in the measurement from 55.7% at T1 to 56.4% at T3. Additionally, patients that did need OS had a significant decrease in mandibular plane angle while patients that did not need OS did not. The difference observed is small, however, this may be an indication that assessing a patient's pattern of mandibular growth as more horizontal or vertical may help guide treatment decisions for efficacy and prognosis of PHG. There are limited studies indicating prognostic factors for PHG therapy in patients with CLP; further studies may be done to investigate which factors contribute towards a favorable long-term prognosis with PHG.

5.1 Limitations

Patients with different expansion appliances and protocols and 26% of patients with no expansion were included in this study due to difficulties in obtaining a large sample. This may introduce confounding factors. Studies have shown that rapid palatal expansion disrupts circumaxillary sutures and its use prior to PHG may facilitate maxillary protraction (Haas 1970, Kim 1999). However, recent data suggests that there are no significant improvements of maxillary protraction with additional expansion (Cordasco 2014, Foersch 2015). Alternating rapid maxillary expansion and constriction with a palatal expander has been used in patients with CLP prior to maxillary protraction with stable results (Liou 2005, Yen 2011). There was no clinically significant difference in maxillary protraction and rotations of the palatal and mandibular planes when compared to standard expansion protocols (Liu 2015). Another limitation is the lack of a control group with no treatment and another cohort of patients that did not receive PHG. This would have provided data representing skeletal measures that occur with and without fixed appliances prior to orthognathic surgery and further clarify the effects of PHG. Additionally, cephalometry presents limitations such as magnification, distortion, and proper patient positioning that could alter the data as not every patient was not standardized into centric relation prior to creating the cephalometric image (Graber 1956). Furthermore, the sample is limited in size and documented from a single center. Given proper standardization of protocols and outcomes, data from other centers that provide similar treatments would have strengthened the study.

5.2 Generalizability

This study included male and female patients starting PHG therapy age 10.5 and under with either complete UCLP or BCLP indicating that these results may be representative, however the results should be applied with caution given the study's limitations. Though compliance was shown to be insignificant in altering the likelihood of OS at our center, these results may bring light to changes in protocol rather than compliance. On average, PHG therapy ceased after approximately 7.4 months of protraction with 1.9 mm of overjet for those that were compliant. It has been previously discussed that overcorrection of 5 to 8 mm as well as molars in Class II should be achieved with successful PHG (Westwood 2003). Additionally, it has been suggested for patients to wear Class III elastics during the day to retain protraction gained when the PGH was not worn (Yen 2011). These are elements that could be incorporated into our protocol and outcomes may be reevaluated for significant differences in the incidence of OS.

5.3 Future research

PHG remains an option for patients in efforts to minimize the likelihood of OS. However, it may not be indicated for every patient in early mixed dentition in patients with CLP and midfacial deficiency. Further research is needed to clarify which variables most likely indicate successful PHG therapy for patients with CLP, including variables related to surgical history such as technique and severity of the initial cleft.

6.0 Conclusion

Compliance with PHG therapy did not significantly decrease the likelihood of OS compared to patients that were noncompliant with PHG. Compliance with PHG proclines and protrudes upper incisors, increases SNA and ANB, decreases SNB, SN-GoGn rotated clockwise, and positive overjet was created; however, overjet, SNA, SNB, and ANB did not remain and changed unfavorably after growth. PHG compliance did not avoid OS for patients with CLP and though it may create short-term favorable skeletal positions and positive overjet, it is not stable.

Bibliography

ACPA Family Services. *For the Parent of Newborns with Cleft Lip and/or Cleft Palate*.

ACPA Family Services. *Prenatal Diagnosis*. 2014.

ACPA Family Services. *The School-aged Child*. 1995.

ACPA Family Services. *Your Baby's First Year*. 2018.

Baccetti, Tiziano, Franchi, Lorenzo, et al. "Cephalometric variables predicting the long-term success or failure of combined rapid maxillary expansion and facial mask therapy." *American Journal of Orthodontics and Dentofacial Orthopedics*. 126.1 (2004): 16 – 22.

Baccetti, Tiziano, McGill, Jean S, et al. "Skeletal effects of early treatment of Class III malocclusion with maxillary expansion and face-mask therapy." *American Journal of Orthodontics and Dentofacial Orthopedics*. 113.3 (1998): 333 – 343.

Baek, Seung-Hak, Kim, Keun-Woo, et al. "New treatment modality for maxillary hypoplasia in cleft patients. Protraction facemask with miniplate anchorage." *Angle Orthodontist*. 80.4 (2010): 783 – 791.

Berkowitz, Samuel. "A Review of Cleft Lip/Palate Literature Reveals That Differential Diagnosis of the Facial Skeleton and Musculature is Essential to Achieve All Treatment Goals." *Journal of Craniofacial Surgery*. 26.4 (2015): 1143 – 1150.

Brattstrom, Viveca, Molsted, Kirsten, et al. "The Eurocleft Study: Intercenter Study of Treatment Outcome in Patients With Complete Cleft Lip and Palate. Part 2 Craniofacial Form and Nasolabial Appearance." *The Cleft Palate-Craniofacial Journal*. 42.1 (2005): 69 – 77.

Cleft Palate Foundation. *As You Get Older*. 2008.

Cleft Palate Foundation. *Genetics and You*. 2008.

Cleft Palate Foundation. *Toddlers and Preschoolers*. 2011

Cordasco, G, Matarese, G, et al. "Efficacy of orthopedic treatment with protraction facemask on skeletal Class III malocclusion: a systematic review and meta-analysis." *Orthodontics & Craniofacial Research*. 17.3 (2014): 133 – 143.

Daskalogiannakis, John, Mercado, Ana, et al. "The Americleft Study: An Inter-Center Study of Treatment Outcomes for Patients with Unilateral Cleft Lip and Palate. Part 3. Analysis of Craniofacial Form." *The Cleft Palate-Craniofacial Journal*. 48.3 (2011): 252 – 258.

Delaire, Jean. “Maxillary development revisited: relevance to orthopaedic treatment of Class III malocclusions.” *European Journal of Orthodontics*. 19.3 (1997): 289 – 311.

Dogan, Servet. “The effects of face mask therapy in cleft lip and palate patients.” *Annals of Maxillofacial Surgery*. 2.2 (2012) 116 – 120.

Enlow, Donald, Hans, Mark. *Essentials of Facial Growth*. 2nd edition. 2008.

Graber, Thomas M. “Problems and limitations of cephalometric analysis in orthodontics.” *The Journal of the American Dental Association*. 53.4 (1956): 439 – 454.

Filho, Leopoldino C, Normando, Antonio DC, et al. “Isolated Influences of Lip and Palate Surgery on Facial Growth: Comparison of Operated and Unoperated Male Adults with UCLP. *The Cleft-Palate Craniofacial Journal*. 33.1 (1996): 51 – 56.

Foersch, Moritz, Jacobs, Collin, et al. “Effectiveness of maxillary protraction using facemask with or without maxillary expansion: a systematic review and meta-analysis.” *Clinical Oral Investigation*. 19.6 (2015): 1181- 1192.

Friede, Hans, Lennartsson, Bertil. “Forward traction of the maxilla in cleft lip and palate patients.” *European Journal of Orthodontics*. 3.1 (1981): 21 – 39.

Haas, Andrew J. “Palatal expansion: Just the beginning of dentofacial orthopedics.” *American Journal of Orthodontics*. 57.3 (1970): 219 – 255.

Han, Byeong-Ju, Suzuki, Akira, et al. “Longitudinal Study of Craniofacial Growth in Subjects with Cleft Lip and Palate: From Cheiloplasty to 8 Years of Age.” *The Cleft-Palate Craniofacial Journal*. 32.2 (1995): 156 – 166.

Hathaway, Ronald, Daskalogiannakis, John, et al. “The Americleft Study: An Inter-Center Study of Treatment Outcomes for Patients with Unilateral Cleft Lip and Palate. Part 2. Dental Arch Relationships.” *The Cleft Palate-Craniofacial Journal*. 48.3 (2011): 44 – 251.

Heidbuhel, Kristin LWM, Kuijpers-Jagtman, Anne M., et al. “Effects of early treatment on maxillary arch development in BCLP. A study on dental casts 0 and 4 years of age.” *Journal of Cranio-Maxillofacial Surgery*. 26.3 (1998): 140 – 147.

Hoefert, Claudia S, Bacher, Margit, et al. “3D Soft Tissue Changes in Facial Morphology in Patients with Cleft Lip and Palate and Class III Malocclusion under Therapy with Rapid Maxillary Expansion and Delaire Facemask.” *Journal of Orofacial Orthopedics*. 71.2 (2010): 136 – 151.

Honda, Yasuo, Suzuki, Akira, et al. “Longitudinal Study on the Changes of Maxillary Arch Dimensions in Japanese Children with Cleft Lip and/or Palate: Infancy to 4 Years of Age.” *The Cleft-Palate Craniofacial Journal*. 32.2 (1995): 149 – 155.

Kim, Jeong-Hwan, Viana, Marlos AG, et al. “The effectiveness of protraction face mask therapy: A meta-analysis.” *American Journal of Orthodontics and Dentofacial Orthopedics*. 115.6 (1999): 675 – 685.

Kobayashi, Shinji, Hirakawa, Takashi, et al. “Maxillary Growth After the Use of Protraction Head Gear in Conjunction With Presurgical Orthopedics and Gingivoperioplasty for Complete Bilateral Cleft Lip and Alveolus Patients.” *Journal of Craniofacial Surgery*. 24.5 (2013): 1679 – 1684.

Lambrecht, JTH, Kreusch, TH, et al. “Position, Shape, and Dimension of the Maxilla in Unoperated Cleft Lip and Palate Patients: Review of the Literature.” *Clinical Anatomy*. 13.2 (2000): 121 – 133.

Latief, Benny S, Kuijpers-Jagtman, Lekkas C. “Maxillary arch width in unoperated adults of the unilateral cleft lip and alveolus patient.” *Journal of Maxillofacial Oral Surgery*. 8.3 (2009) 218 – 220.

Liao, Yu-Fang, Mars, Michael. “Long-Term Effects of Palate Repair on Craniofacial Morphology in Patients With Unilateral Cleft Lip and Palate.” *The Cleft Palate-Craniofacial Journal*. 42.6 (2005): 594 – 600.

Liou, Eric JW, Tsai, Wen-Ching. “A New Protocol for Maxillary Protraction in Cleft Patients: Repetitive Weekly Protocol of Alternate Rapid Maxillary Expansions and Constrictions.” *The Cleft Palate-Craniofacial Journal*. 42.2 (2005): 121 – 127.

Liu, Weitao, Zhou, Yanheng, et al. “Effect of maxillary protraction with alternating rapid palatal expansion and constriction vs expansion alone in maxillary retrusive patients: A single-center, randomized controlled trial.” *American Journal of Orthodontics and Dentofacial Orthopedics*. 148.4 (2015): 641 – 651.

Long, Jr, Ross E, Hathaway, Ronald, et al. “The Americleft Study: An Inter-Center Study of Treatment Outcomes for Patients with Unilateral Cleft Lip and Palate. Part 1. Principles and Study Design.” *The Cleft Palate-Craniofacial Journal*. 48.3 (2011): 239 – 43.

Mandall, Nicky, Cousley, Richard, et al. “Early class III protraction facemask treatment reduces the need for orthognathic surgery: a multi-centre, two-arm parallel randomized, controlled trial.” *Journal of Orthodontics*. 43.3 (2016) 164 – 175.

Mars, Michael, Houston, William JB. “A Preliminary Study of Facial Growth and Morphology in Unoperated Male Unilateral Cleft Lip and Palate Subjects Over 13 Years of Age.” *The Cleft Palate Journal*. 27.1 (1990): 7 – 10.

Mars, Michael, Plint, Dennis A, et al. “The Goslon Yardstick: A New System of Assessing Dental Arch Relationships in Children with Unilateral Clefts of the Lip and Palate.” *The Cleft Palate Journal*. 24.4 (1987) 314 – 322.

Mercado, Ana, Russell, Kathleen, et al. "The Americleft Study: An Inter-Center Study of Treatment Outcomes for Patients with Unilateral Cleft Lip and Palate. Part 4. Nasolabial Aesthetics." *The Cleft Palate-Craniofacial Journal*. 48.3 (2011): 259 – 264.

Molsted, Kirsten, Brattstrom, Viveca, et al. The Eurocleft Study: Intercenter Study of Treatment Outcome in Patients With Complete Cleft Lip and Palate. 3: Dental Arch Relationships" *The Cleft Palate-Craniofacial Journal*. 42.1 (2005): 78 – 82.

Naqvi, Zuber A, Shivalinga, BM, et al. "Effect of cleft lip palate repair on craniofacial growth." *Journal of Orthodontic Science*. 4.3 (2015): 59 – 64.

Nardoni, Daniele N, Siqueira, Danilo F, et al. "Cephalometric variables used to predict the success of interceptive treatment with rapid maxillary expansion and face mask. A longitudinal study." *Dental Press Journal of Orthodontics*. 20.1 (2015): 85 – 96.

Proffit, William R, Fields, Henry W, et al. *Contemporary Orthodontics*. Fifth edition. Elsevier Mosby, 2013.

Richardson, Sunil, Krishna, Shreya, et al. "A comprehensive management protocol to treat cleft maxillary hypoplasia." *Journal of Cranio-Maxillo-Facial Surgery*. 46.2 (2018): 356 – 361.

Ross, RB. "The Clinical Implications of Facial Growth in Cleft Lip and Palate." *The Cleft Palate Journal*. 7.1 (1970): 37 – 47.

Ross, RB. "Treatment Variables affecting Facial Growth in Complete Unilateral Cleft Lip and Palate. Part 1: Treatment Affecting Growth." *The Cleft Palate Journal*. 23.1 (1987): 5 – 23.

Ross, RB. "Treatment Variables affecting Facial Growth in Complete Unilateral Cleft Lip and Palate. Part 2: Presurgical Orthopaedics." *The Cleft Palate Journal*. 23.1 (1987): 24 – 32.

Ross, RB. "Treatment Variables affecting Facial Growth in Complete Unilateral Cleft Lip and Palate. Part 3: Alveolus Repair and Bone Grafting." *The Cleft Palate Journal*. 23.1 (1987): 33 – 44.

Ross, RB. "Treatment Variables affecting Facial Growth in Complete Unilateral Cleft Lip and Palate. Part 4: Repair of the Cleft Lip." *The Cleft Palate Journal*. 23.1 (1987): 45 – 53.

Ross, RB. "Treatment Variables affecting Facial Growth in Complete Unilateral Cleft Lip and Palate. Part 5: Timing of Palate Repair." *The Cleft Palate Journal*. 23.1 (1987): 54 – 63.

Ross, RB. "Treatment Variables affecting Facial Growth in Complete Unilateral Cleft Lip and Palate. Part 6: Techniques of Palate Repair." *The Cleft Palate Journal*. 23.1 (1987): 64 – 70.

Ross, RB. "Treatment Variables affecting Facial Growth in Complete Unilateral Cleft Lip and Palate. Part 7: An Overview of Treatment and Facial Growth." *The Cleft Palate Journal*. 23.1 (1987): 71 – 77.

Russell, Kathleen, Long, Jr, Ross E, et al. "The Americleft Study: An Inter-Center Study of Treatment Outcomes for Patients with Unilateral Cleft Lip and Palate. Part 5. General Discussion and Conclusions." *The Cleft Palate-Craniofacial Journal*. 48.3 (2011): 265 – 270.

Semb, Gunvor, Brattstrom, Viveca, et al. "The Eurocleft Study: Intercenter Study of Treatment Outcome in Patients With Complete Cleft Lip and Palate. Part 1: Introduction and Treatment Experience." *The Cleft Palate-Craniofacial Journal*. 42.1 (2005): 64 – 68.

Semb, Gunvor, Brattstrom, Viveca, et al. "The Eurocleft Study: Intercenter Study of Treatment Outcome in Patients With Complete Cleft Lip and Palate. Part 4: Relationship Among Treatment Outcome, Patient/Parent Satisfaction, and the Burden of Care." *The Cleft Palate-Craniofacial Journal*. 42.1 (2005): 83 – 92.

Shaw, William C., Brattstrom, Viveca, et al. "The Eurocleft Study: Intercenter Study of Treatment Outcome in Patients With Complete Cleft Lip and Palate. Part 5: Discussion and Conclusions." *The Cleft Palate-Craniofacial Journal*. 42.1 (2005): 93 – 98.

Shetye, Pradip R. "Facial growth of adults with unoperated clefts." *Clinics in Plastic Surgery*. 31.2 (2004): 361 – 371.

Shi, Bing, Losee, Joseph E. "The impact of cleft lip and palate repair on maxillofacial growth." *International Journal of Oral Science*. 7.1 (2015): 14 – 17.

Susami, Takafumi, Okayasu, Mari, et al. "Maxillary Protraction in Patients With Cleft Lip and Palate in Mixed Dentition: Cephalometric Evaluation After Completion of Growth." *The Cleft Palate-Craniofacial Journal*. 51.5 (2014): 514 – 524.

The Washington State Department of Health Children and Youth with Special Health Care Needs Program, Seattle Children's Hospital Craniofacial Center. *Cleft Lip and Palate. Critical Elements of Care*. 2018.

Tindlund, Rolf S, Rygh, Per, et al. "Orthopedic Protraction of the Upper Jaw in Cleft Lip and Palate Patients during the Deciduous and Mixed Dentition Periods in Comparison with Normal Growth and Development." *The Cleft Palate-Craniofacial Journal*.30.2 (1993): 182 – 194.

Tindlund, Rolf S. "Skeletal Response to Maxillary Protraction in Patients with Cleft Lip and Palate before Age 10 Years." *The Cleft Palate-Craniofacial Journal*. 31.4 (1994): 295 – 308.

Wells, Andrew P, Sarver, David M, et al. "Long-term Efficacy of Reverse Pull Headgear Therapy." *Angle Orthodontist*. 76.6 (2006): 915 – 922.

Westwood, Patricia V, McNamara Jr, James A, et al. "Long-term effects of Class III treatment with rapid maxillary expansion and facemask therapy followed by fixed appliances." *American Journal of Orthodontics and Dentofacial Orthopedics*. 123.3 (2003): 306 – 320.

Woon, See C, Thiruvenkatachari, Badri. “Early orthodontic treatment for Class III malocclusion: A systematic review and meta-analysis.” *American Journal of Orthodontics and Dentofacial Orthopedics*. 151.1 (2017): 28 – 52.

Worley, Mitchell L, Patel, Krishna G, et al. “Cleft Lip and Palate.” *Clinical Perinatology*. 45.4 (2018): 661 – 678.

Yen, Stephen LK. “Protocols for Late Maxillary Protraction in Cleft Lip and Palate Patients at Children’s Hospital of Los Angeles.” *Seminars in Orthodontics*. 17.2 (2011): 138 – 148.